General information on the preparation (cleaning, disinfection and sterilisation) of BOWA surgical handles and cables

Unsterile instruments must not be used without previous cleaning/disinfection and sterilisation. Effective cleaning/disinfection is an essential prerequisite for effective sterilisation of the instruments.

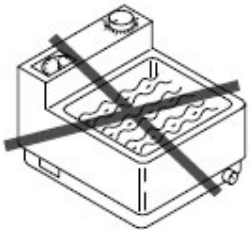
As part of your responsibility for ensuring that instruments are sterile in use, it must be ensured that only adequately validated methods specific to the device and the product are used for cleaning/disinfection and sterilisation, and that the validated parameters are maintained in each cycle.

The laws applicable in your country and the hygiene regulations of the hospital/clinic must be observed.

1. Soaking

Soaking must be carried out immediately after use (within a maximum of 2 hours). Use only aldehyde-free disinfectants for this purpose (otherwise setting of blood contamination) with proven effectiveness (e.g. DGHM or FDA approval or CE marking), which are suitable for disinfecting instruments and which are compatible with the instruments.

A synthetic fleece or plastic cleaning brush can be used if necessary for the preliminary removal of residues.



Ultrasonic bath

Do not pre-clean HF cables and handles in the ultrasonic bath.

NOTE
The disinfectant used for soaking is only intended for protecting personnel and cannot replace the later disinfecting step after cleaning has been carried out.

2. Removal/dismantling

Instruments that can be taken apart must be dismantled in accordance with the appropriate instruction manual for further cleaning.

3. Cleaning/disinfecting

An automatic process should be used for cleaning/disinfecting the instruments (disinfector). A manual process is not recommended due to the considerably lower effectiveness.

BOWA recommends the use of neutral to slightly alkaline cleaning agents or combined cleaning agents and disinfectants without critical ingredients (depending on the

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concentration). Alcoholic and/or aldehydic ingredients should preferably be used, as these do not attack the materials used by BOWA so severely.

Discolouration of metal surfaces is possible when alkaline cleaners are used (pH 9.5 - 11.5). However, this does not impair the functional capability of the product. Strong alkaline cleaners (pH > 11.5) must be avoided.

The suitability of the products for effective cleaning/disinfection has been proved by BOWA with the automatic method (93°C, 10 min) using an alkaline cleaning agent with tenside additive (neodisher® mediclean forte with neodisher® mediklar).

The use of other cleaning agents/disinfectants is outside the manufacturer's responsibility. In this case, written agreement must be obtained from the manufacturer.

When choosing the disinfector, it must be ensured
- that the disinfector fundamentally has proven effectiveness (e.g. DGHM or FDA approval or CE marking according to DIN EN ISO 15883),
- that a tested program for thermal disinfection (at least 10 min at 93 °C or A_0 value > 3000) is used if possible (with chemical disinfection there is a risk of disinfectant residues on the instruments),
- that the program used is suitable for the instruments and includes sufficient rinsing cycles,
- that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water is used,
- that the air used for drying is filtered, and
- that the disinfector is regularly maintained and tested.

When choosing the disinfection system to be used, it must be ensured
- that this is basically suitable for cleaning the instruments,
- that - if thermal disinfection is not used – a suitable disinfectant with proven effectiveness (e.g. DGHM or FDA approval or CE marking) is used in addition, and that this is compatible with the cleaning medium used, and
- that the chemicals used are compatible with the instruments.

It is essential that the concentrations and reaction times specified by the manufacturer of the cleaning and if applicable disinfection media be maintained.

Procedure:
1. Place the instruments in the disinfector. In doing so, make sure that the cables are not kinked or crushed.
2. Start the program.
3. Remove the instruments from the disinfector at the end of the program.
4. Check and pack the instruments immediately after removal if possible (after additional drying in a clean place).

Blow out with filtered compressed air if necessary.
In order to avoid possible damage, dry products with compressed air at < 3 bar only.

4. Checking

Check products for operation and visible damage in accordance with the appropriate instruction manual.

In the case of moving or swivelling parts (e.g. the handles of forceps), BOWA recommends that the use of instrument oil be avoided (exception: surgical instruments made from stainless steel), as certain plastics tend to swell and the free movement may even be impeded as a result of oiling.

5. Packing

Before sterilisation, the dismantled instruments must be packed in a suitable single-use sterilisation pack (single or double pack) and/or a suitable sterilisation container:

- in accordance with DIN EN 868/ANSI AAMI ISO 11607
- suitable for steam sterilisation (temperature resistance up to 137°C, adequate steam permeability)
- regularly maintained (sterilisation container)

NOTE
Sterilisation in the transport packaging is not permissible.

6. Autoclaving

Instruments may only be sterilised in a dismantled condition.

Only the sterilisation methods listed below must be used for sterilisation; other sterilisation methods are not permissible.

Steam sterilisation

- Fractionated vacuum process[1] (with adequate product drying)
- Steam steriliser in accordance with DIN EN 13060 or DIN EN 285
- Validated in accordance with DIN EN 554/ANSI AAMI ISO 11134 (valid commissioning and product-specific performance assessment)
- Maximum sterilisation temperature 134°C (plus tolerance according to DIN EN 554/ANSI AAMI ISO 11134)
- Sterilisation time at least 20 min (at 121°C) or 5 to 20 min at 132/134°C

[1] The use of the less effective gravitation method must be safeguarded by additional validation (longer sterilisation times may be necessary).

The suitability of the products for effective sterilisation has been proved by BOWA using the fractionated vacuum method with the above sterilisation times/temperatures.

The basic suitability of the instruments for effective steam sterilisation has been proved by means of an independent accredited test laboratory using the fractionated vacuum method (EuroSelectomat from the company MMM Münchener Medizin Mechanik GmbH, Planegg). The method described above was taken into account here.

The hot air sterilisation method must not be used as a basic principle (damage to instruments).

The use of other sterilisation methods (e.g. ethylene oxide, formaldehyde, radiation and low-temperature plasma sterilisation) is outside the manufacturer's responsibility. In this case, the respectively applicable standards must be taken into account (DIN EN ISO 14937/ANSI AAMI ISO 14937 and process-specific standards), and evidence must be provided of the suitability and effectiveness in principle of the process (including tests of the sterilisation medium if necessary) taking into account the specific product geometry as part of the validation.

7. Store for use

8. Assemble parts/Check/Functional test in operating theatre

The dismantled instruments must be assembled for use in accordance with the appropriate instruction manual. A visual and functional inspection must be carried out each time before use.

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